the contractor shall notify the contracting officer of the refusal.

FAR 52.227–21, Technical Data Declaration, Revision, and Withholding of Payment–Major Systems. This clause requires major systems contractors to certify that the data delivered under the contract is complete, accurate, and compliant with the requirements of the contract.

FAR 52.227–23, Rights to Proposal Data (Technical). This clause allows the Government to identify pages of a proposal that would not be subject to unlimited rights in the technical data.

The information collected is used to protect the Government's rights and interests.

C. Annual Burden

Respondents/Recordkeepers: 830.

Total Annual Responses: 14,848.

Total Burden Hours: 55,600. (54,673 reporting hours + 927 recordkeeping hours).

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 9000–0095, Federal Acquisition Regulation Part 27 Requirements.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

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BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–5997]

Biosimilar User Fee Act; Stakeholder Consultation Meetings on Biosimilar User Fee Act Reauthorization; Request for Notification of Stakeholder Intention To Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders—including patient and consumer advocacy groups—notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Biosimilar User Fee Act (BsUFA). The statutory authority for BsUFA expires in September 2027. At that time, new legislation will be required for FDA to continue collecting biosimilar biological product user fees in future fiscal years. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next BsUFA program. The FD&C Act also requires that FDA hold discussions at least once every month with patient and consumer advocacy groups during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings by January 30, 2026. Stakeholder meetings will be held monthly. It is anticipated that they will commence in April 2026. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: Submit notification of intention to participate in monthly stakeholder meetings by email to *BSUFAReauthorization@fda.hhs.gov.* The meetings will be held in person at the FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, and virtually using the Microsoft Teams platform. In-person participants must be REAL ID compliant to access federal facilities. For additional information regarding REAL ID, refer to *https://www.dhs.gov/real-id/real-id-faqs.* Entrance for the stakeholder meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

FOR FURTHER INFORMATION CONTACT: Thamar Bailey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 32, Rm. 4103, Silver Spring, MD 20993–0002, 301–796–6645, *BSUFAReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that public stakeholders—including patient and consumer advocacy groups—notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of BsUFA. BsUFA authorizes FDA to collect user fees from the regulated industry to support the process for the review of biosimilar biological products. The authorization for the current program (BsUFA III) expires in September 2027. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years.

Section 744I(f)(1) of the FD&C Act (21 U.S.C. 379j-53(f)(1)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer advocacy groups, in developing recommendations for the next BsUFA program. FDA will initiate the reauthorization process by holding a public meeting on December 3, 2025, where stakeholders and other members of the public will be given an opportunity to present their views on the reauthorization (90 FR 52967, November 24, 2025). Section 744I(f)(3) of the FD&C Act (21 U.S.C. 379j–53(f)(3)) further requires that FDA continue meeting with representatives from patient and consumer advocacy groups at least once every month during negotiations with the regulated industry to continue discussions of these stakeholders' views on the reauthorization. It is anticipated that these monthly stakeholder consultation meetings will commence in April 2026.

FDA is issuing this **Federal Register** notice to request that representatives from patient and consumer advocacy groups notify FDA of their intent to participate in the periodic stakeholder consultation meetings on BsUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in these stakeholder consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions. Stakeholders who identify themselves through this notice will be included in all patient and consumer advocacy group stakeholder consultation discussions while FDA negotiates with the regulated industry. If a representative from a patient or consumer advocacy group decides to participate in these monthly meetings at a later time, that stakeholder may join the remaining monthly patient and consumer advocacy group stakeholder consultation meetings after notifying FDA of this intention (see **ADDRESSES**). These stakeholder discussions will satisfy the consultation requirement in section 744I(f)(3) of the FD&C Act.

II. Notification of Intent To Participate in Periodic Patient and Consumer Advocacy Group Stakeholder Consultation Meetings

If you intend to participate in these continued periodic stakeholder consultation meetings regarding BsUFA reauthorization, please provide notification by email to *BSUFAReauthorization@fda.hhs.gov* by January 30, 2026. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting after FDA receives this notification. Information concerning BsUFA, including the text of the law, the BsUFA III Commitment Letter, key **Federal Register** documents, BsUFA-related guidances, performance reports, and financial reports may be found on the FDA website at *https://www.fda.gov/industry/fda-user-fee-programs/biosimilar-user-fee-amendments.*

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22619 Filed 12–11–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–6077]

Pfizer Inc., U.S. Agent for King Pharmaceuticals LLC, et al.; Withdrawal of Approval of 20 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 20 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 12, 2026.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
ANDA 040320	TAPAZOLE (methimazole) tablets, 5 milligrams (mg) and 10 mg.	Pfizer Inc., U.S. Agent for King Pharmaceuticals LLC, 66 Hudson Blvd. East, New York, NY 10001.
ANDA 060582	NEOSPORIN (gramicidin; neomycin sulfate; polymyxin B sulfate) solution/drops, 0.025 mg/milliliter (mL); Equivalent to (EQ) 1.75 mg base/mL; 10,000 units/mL.	Pfizer Inc., U.S. Agent for Monarch Pharmaceuticals, LLC, a subsidiary of Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001.
ANDA 060707	NEOSPORIN G.U. Irrigant (neomycin sulfate; polymyxin B sulfate) solution, EQ 40 mg base/mL; 200,000 units/mL.	Do.
ANDA 062310	HUMATIN (paromomycin sulfate) capsule, EQ 250 mg base	Pfizer Inc., U.S. Agent for Monarch Pharmaceuticals, LLC.
ANDA 062414	Gentamicin Sulfate in sodium chloride 0.9% in plastic container, injectable, EQ 1.2 mg base/mL, EQ 1.4 mg base/mL, EQ 1.6 mg base/mL, EQ 1.8 mg base/mL, EQ 2 mg base/mL, EQ 60 mg base/100 mL, EQ 70 mg base/100 mL, EQ 80 mg base/100 mL, EQ 90 mg base/100 mL, and EQ 100 mg base/100 mL.	Hospira, Inc., 275 North Field Dr., Building H1–3S, Lake Forest, IL 60045.
ANDA 063165	ADRIAMYCIN PFS (doxorubicin HCl) injectable, 2 mg/mL and 200 mg/100 mL.	Pfizer Inc.
ANDA 072320	Pancuronium Bromide injectable, 1 mg/mL	Hospira, Inc.
ANDA 075221	ALFENTANIL (alfentanil HCl) injectable, EQ 0.5 mg base/mL	Do.
ANDA 075458	Enalaprilat injectable, 1.25 mg/mL	Do.
ANDA 075885	Milrinone Lactate in Dextrose 5% in plastic container, injectable, EQ 20 mg base/100 mL (EQ 0.2 mg base/mL) and EQ 40 mg base/200 mL (EQ 0.2 mg base/mL).	Do.
ANDA 076304	Fluconazole in Dextrose 5% in plastic container, injectable, 200 mg/100 mL (2mg/mL) and 400 mg/200 mL (2 mg/mL).	Do.
ANDA 077394	Sodium Bicarbonate injectable, 0.9 milliequivalent (mEq)/mL and 1 mEq/mL.	Do.
ANDA 089070	Procainamide HCl injectable, 500 mg/mL	Do.
ANDA 090621	Zoledronic Acid injectable, EQ 4 mg base/5 mL	Do.
ANDA 202837	Zoledronic Acid injectable, EQ 5 mg base/100 mL	Do.
ANDA 203709	Fludeoxyglucose F 18 injectable, 20–500 millicurie (mCi)/mL	B&H Consulting Services, Inc., U.S. Agent for Wisconsin Medical Radiopharmacy, LLC, 50 Division St., Suite 206, Somerville, NJ 08876.
ANDA 203883	Adenosine solution, 60 mg/20 mL (3mg/mL) and 90 mg/30 mL (3 mg/mL).	Hospira, Inc.
ANDA 204118	Indomethacin Sodium injectable, EQ 1 mg base/vial	Do.
ANDA 208016	Lurasidone HCl tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg.	Watson Laboratories, Inc. (an indirect, wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054.